combine references. Second, there must be a reasonable expectation of success. Third, the references must teach or suggest all the claim elements. *See* M.P.E.P. § 2143. Moreover, the requisite teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). *See* M.P.E.P. § 706.02(j).

As Applicants noted in a previous Amendment, Winston discloses a stent and placement system that includes a spool 12, one or more flanges 14 formed on the spool 12, and a stent 10 adjacent to and abutting each flange 14. Stent 10 is formed from a solid sheet 11 that is wrapped several times to provide several layers. Spool 12, its flange(s) 14, and stent(s) 10 are placed within an outer elongated sheath 20. The entire outer surfaces of stent(s) 10 and flange(s) 14 completely contact the inner surface of sheath 20. No gap, or clearance, exists between flange(s) 14 and sheath 20. In addition, Winston has no teaching or suggestion of flanges 14 have varying durometer measurements, of a translucent distal region on sheath 20, or a marker band on spool 12. None of the combinations proposed by the Examiner meet the *prima facie* requirement of obviousness for the pending claims.

Rejection of claims 14-18 and 24-28

Claims 14-18 and 24-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Winston in view of Lukic. By this Amendment, claims 14, 17, 18, 24, 27, and 28, have been cancelled, without prejudice or disclaimer. Claims 15 and 16 have been amended to depend from claim 19, and claims 25 and 26 have been amended to depend from claim 29. Therefore, this rejection is moot.

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Rejection of Claims 10-12, 44, and 45

Claims 10-12, 44, and 45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Winston in view of Mikus. By this Amendment, claims 10 and 44 have been cancelled, without prejudice or disclaimer, and claims 11 and 45 have been rewritten in independent form. Each of claims 11 and 45 recite an outer tubular structure having a translucent region having a length that substantially coincides with a constrained length of a stent within the outer tubular structure. As discussed in the specification, these structural elements allow a user to view the distal portion of an inner structure carrying a stent when that distal portion is near the distal end of the outer tubular structure. This can signal to the user that the stent is about to be deployed. In addition, as described in the specification, having only the most distal portion of the outer tubular structure translucent permits the more proximal sections to be made of materials of different characteristics more suitable for endoscopic use. For example, the proximal section may be formed of a relatively stiff, strong material and the distal region may be formed of a flexible, clear material. See specification, page 14, lines 11-16.

The Examiner alleges that it would have been obvious to one of ordinary skill in the art to modify Winston to include a translucent outer tubular structure taught by Mikus "in order to enable an endoscope to view markings 47, 48 used to measure the prostate gland." Applicants respectfully disagree with this assertion.

Mikus discloses a stent delivery system including a stent 10 located on a distal portion of a delivery catheter 11. A catheter sheath 13, transparent along its entire length, is provided over an endoscope and inside the urethra. The catheter sheath 13

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includes a distal marking 47 and ruled markings 48, which are used to measure the prostate gland. Once the prostate gland is measured, an appropriate sized stent is provided. See col. 8, lines 1-19.

Claim 11 directed to a system and claim 45 directed to a method of deploying a stent, each requires that the translucent region have a length that substantially coincides with a constrained length of a stent. The Examiner's proposed combination of Winston and Mikus fails to teach this limitation because the entire catheter sheath 13 is transparent. Moreover, one of ordinary skill in the art would not be motivated to modify Winston further to provide a translucent region with a length that substantially coincides with a constrained length of a stent because Mikus uses the catheter sheath 13 to measure the prostate gland and the size of the gland will vary. Therefore, the Section 103 rejection of claims 11 and 45 must be withdrawn.

Claim 12 depends from claim 5, which was not rejected under Winston in view of Mikus, and therefore this rejection should be withdrawn.

Rejection of Claims 1-4 and 34-38

Claims 1-4 and 34-38 were rejected 35 U.S.C. § 103(a) as being unpatentable over Winston in view of Lukic and Mikus. By this Amendment, claims 1, 3, 4, 34, 37, and 38, have been cancelled, without prejudice or disclaimer. Claim 2 has been amended to depend from claim 5 and claims 35 and 36 have been amended to depend from claim 39. Therefore, this rejection is moot.

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Claims 5-9, 19-23, 29-33, and 39-43

Claims 5-9, 19-23, 29-33, and 39-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Winston in view of Burns. Applicants respectfully disagree with this rejection.

Claim 5 recites a system for delivering a stent including, among other things, an inner elongated structure having a plurality of external tubular structure contact areas projecting from its surface. Each of the contact areas is separated from the others, and the durometer increases for each subsequent contact area from the distal end to the proximal end. Claims 19, 29, and 39 recite similar recitations. As discussed in the specification, this claim feature promotes flexibility in the delivery system near the distal end where the device may require a greater degree of precision in winding through tortuous anatomy.

Burns discloses an angioplasty catheter where a distal **outer tube** section 20 is, in a preferred embodiment, high density polyethylene and a proximal **outer tube** section 18 is formed of either stainless steel or polyimide. A distal **inner tube** section 24 is a polyimide tube that has a smaller inner and outer diameter than a proximal **inner tube** section 22, which may be formed of the same material as the distal **inner tube**. See col. 3, lines 49-51; col. 3, line 65 to col. 4, line 6; and col. 4, lines 24-36. Therefore, Burns discloses that to vary flexibility of the outer tube, different materials may be used. But to vary flexibility of the inner tube, Burns only teaches to employ different size diameters. Even with the knowledge that the outer tube could be made of different materials to vary flexibility, Burns teaches to use the same material throughout the inner tube and vary flexibility of the inner tube in a different way—by varying diameter.

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Therefore, one of ordinary skill in the art would not look to Burns to modify the flange(s) 14 of the spool of Winston to provide different durometer measurements.

Moreover, as discussed in a previous Amendment, the depiction in the Figures of very narrow flanges 14 suggests that even if the durometer measurement of flanges 14 were varied, there would be little or no effect on the overall flexibility of the spool 12 in Winston. One skilled in the art desiring to make the distal end of the spool 12 more flexible in any appreciable way would not simply vary the material of the flanges 14 because of their relatively narrow size.

For at least these reasons, the Section 103 rejection of claims 5, 19, 29, and 39 should be withdrawn.

The Section 102 Rejection

Claims 13 and 46 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hofmann. By this Amendment, claims 13 and 46 have been amended to depend from claims 5 and 39, respectively. Therefore, these claims are allowable for at least the same reasons as the independent claims from which they depend.

Conclusion

In view of these amendments and remarks, Applicants request the reconsideration of this application and the allowance of the pending claims.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: May 13, 2003

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APPENDIX TO AMENDMENT

Amendments to the claims:

2. (Amended) The system of claim [1] 5, wherein the external tubular structure contact [area] areas on the inner elongated structure [is] are constructed of Pellethane.

11. (Amended) A system for delivering a stent into an anatomical structure, the system comprising:

an outer tubular structure having a proximal end and a distal end, wherein the outer tubular structure has a translucent region at its distal end and [The system of claim 10, wherein] the translucent region has a length that substantially coincides with a constrained length of a stent within the outer tubular structure;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure; and

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area frictionally sliding against an interior surface of the outer tubular structure.

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12. (Amended) The system of claim [1] 5, further comprising a stent located in the stent accommodating area and within the outer tubular structure when the stent is constrained.

13. (Twice Amended) The system of claim 5, further comprising: [A system for delivering a stent into an anatomical structure, the system comprising:

an outer tubular structure having a proximal end and a distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure;

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area able to frictionally slide against an interior surface of the outer tubular structure; and]

a gap between an external surface of the external tubular structure and the interior surface of the outer tubular structure.

15. (Amended) The structure of claim [14] 19, further comprising:

a stent positioned in the stent accommodating area.

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16. (Amended) The structure of claim [14] 19, wherein the engagement [area] areas on the elongated structure [is] are constructed of Pellethane.

25. (Amended) The structure of claim [24] 29, further comprising:

a stent positioned in the stent accommodating means.

26. (Amended) The structure of claim [24] 29, wherein the engagement means on the elongated structure is constructed of Pellethane.

35. (Amended) The method of claim [34] 39, further comprising:

before completely deploying the stent into the anatomical structure, moving the inner elongated structure proximally while maintaining the position of the outer tubular structure, thus retracting the at least part of the stent from the anatomical structure back into the stent accommodating area; and

re-positioning the stent delivery system to a new position with respect to the anatomical structure.

36. (Amended) The method of claim [34] 39, wherein the external tubular structure contact [area] areas on the inner elongated structure [is] are constructed of Pellethane.

45. (Amended) A method of deploying a stent with respect to an anatomical structure, the method comprising:

providing a stent delivery system, the system comprising:

an outer tubular structure having a proximal end and a distal end, wherein the outer tubular structure has a translucent region at its distal end and [The method of claim 44, wherein] the translucent region has a

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length that substantially coincides with a constrained length of a stent within the outer tubular structure;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure accommodating a stent; and

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area able to frictionally slide against an interior surface of the outer tubular structure;

inserting the stent delivery system through an insertion point in a body until the distal ends of the external tubular structure and the inner elongated structure are in a position within the anatomical structure;

moving the outer tubular structure proximally while maintaining the position of the inner elongated structure, thus exposing the stent accommodating area and releasing at least part of the stent into the anatomical structure;

continuing the proximal movement of the outer tubular structure with respect to the inner elongated structure until the stent is completely deployed into the anatomical structure; and

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withdrawing the stent delivery system from the insertion point in the body.

46. (Twice Amended) The method of claim 39, wherein the stent delivery system further comprises: [A method of deploying a stent with respect to an anatomical structure, the method comprising:

providing a stent delivery system, the system comprising:

an outer tubular structure having a proximal end and a distal end;

an inner elongated structure having a proximal end and a distal end, the inner elongated structure being located within the outer tubular structure such that the distal end of the inner elongated structure substantially coincides with the distal end of the outer tubular structure;

a stent accommodating area on the distal end of the inner elongated structure accommodating a stent;

an external tubular structure contact area projecting from a surface of the inner elongated structure and located proximal to the stent accommodating area, the external tubular structure contact area able to frictionally slide against an interior surface of the outer tubular structure; and]

a gap between an external surface of the external tubular structure and the interior surface of the outer tubular structure[;

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inserting the stent delivery system through an insertion point in a body until the distal ends of the external tubular structure and the inner elongated structure are in a position within the anatomical structure;

moving the outer tubular structure proximally while maintaining the position of the inner elongated structure, thus exposing the stent accommodating area and releasing at least part of the stent into the anatomical structure;

continuing the proximal movement of the outer tubular structure with respect to the inner elongated structure until the stent is completely deployed into the anatomical structure; and

withdrawing the stent delivery system from the insertion point in the body].

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